IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

IN RE: C. R. BARD, INC.,
PELVIC REPAIR SYSTEM
PRODUCTS LIABILITY LITIGATION MDL No. 2187

THIS DOCUMENT RELATES TO C. R. BARD WAVE 4 & WAVE 5 CASES BEFORE JUDGE GOODWIN:

MEMORANDUM OPINION AND ORDER
(*Daubert* Motion re: Patrick Culligan, M.D.)

Pending in *In re C. R. Bard, Inc.*, *2:10-md-2187*, MDL 2187, is the plaintiffs' *Daubert* Motion to Exclude Certain Opinions and Testimony of Patrick Culligan [ECF No. 4563]. The motion is now ripe for consideration because the briefing is complete. As set forth below, the plaintiffs' motion is **GRANTED in part**, **DENIED in part**, and **RESERVED in part**.

I. Background

This case resides in one of seven MDLs assigned to me by the Judicial Panel on Multidistrict Litigation concerning the use of transvaginal surgical mesh to treat pelvic organ prolapse ("POP") and stress urinary incontinence ("SUI"). In the seven MDLs, there are more than 16,000 cases currently pending, approximately 1,500 of which are in the Bard MDL, 2187 MDL.

In this MDL, the court's tasks include "resolv[ing] pretrial issues in a timely and expeditious manner" and "resolv[ing] important evidentiary disputes." Barbara

J. Rothstein & Catherine R. Borden, Fed. Judicial Ctr., *Managing Multidistrict Litigation in Products Liability Cases* 3 (2011). In an effort to manage the massive Bard MDL efficiently and effectively, the court decided to conduct pretrial discovery and motions practice on an individualized basis. To this end, I selected certain cases to become part of a "wave" of cases to be prepared for trial and, if necessary, remanded.

Upon the creation of a wave, a docket control order subjects each case in the wave to the same scheduling deadlines, rules regarding motion practice, and limitations on discovery. *See, e.g.*, Pretrial Order ("PTO") # 236 (establishing Wave 4); PTO # 244 (establishing Wave 5). To handle motions to exclude or to limit expert testimony pursuant to *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), the court developed a specific procedure for cases designated in Wave 4 and Wave 5. The court instructed the parties to file briefing on general causation issues in the main MDL, MDL 2187, while specific causation *Daubert* motions, responses, and replies were to be filed in the individual member cases. To the extent that an expert is both a general and specific causation expert, the court advised the parties that they could file a general causation motion in the main MDL and a specific causation motion in an individual member case. *See* PTO # 236, at 4; PTO # 244, at 4.

II. Legal Standard

Under Federal Rule of Evidence 702, expert testimony is admissible if it will "help the trier of fact to understand the evidence or to determine a fact in issue" and

(1) is "based upon sufficient facts or data" and (2) is "the product of reliable principles and methods" which (3) has been reliably applied "to the facts of the case." Fed. R. Evid. 702. A two-part test governs the admissibility of expert testimony. The evidence is admitted if it "rests on a reliable foundation and is relevant." *Daubert v. Merrell Dow Pharm.*, 509 U.S. 579, 597 (1993). The proponent of expert testimony does not have the burden to "prove" anything. However, he or she must "come forward with evidence from which the court can determine that the proffered testimony is properly admissible." *Md. Cas. Co. v. Therm-O-Disc, Inc.*, 137 F.3d 780, 783 (4th Cir. 1998).

The district court is the gatekeeper. It is an important role: "[E]xpert witnesses have the potential to be both powerful and quite misleading"; the court must "ensure that any and all scientific testimony . . . is not only relevant, but reliable." *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 199 (4th Cir. 2001) (citing *Daubert*, 509 U.S. at 588, 595; *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 261 (4th Cir. 1999)). I "need not determine that the proffered expert testimony is irrefutable or certainly correct" – "[a]s with all other admissible evidence, expert testimony is subject to testing by '[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof.'" *United States v. Moreland*, 437 F.3d 424, 431 (4th Cir. 2006) (alteration in original) (quoting *Daubert*, 509 U.S. at 596 (alteration in original)); *see also Md. Cas. Co.*, 137 F.3d at 783 ("All *Daubert* demands is that the trial judge make a 'preliminary assessment' of whether the proffered testimony is both reliable . . . and helpful.").

Daubert mentions specific factors to guide the overall relevance and reliability determinations that apply to all expert evidence. They include (1) whether the particular scientific theory "can be (and has been) tested"; (2) whether the theory "has been subjected to peer review and publication"; (3) the "known or potential rate of error"; (4) the "existence and maintenance of standards controlling the technique's operation"; and (5) whether the technique has achieved "general acceptance" in the relevant scientific or expert community. *United States v. Crisp*, 324 F.3d 261, 266 (4th Cir. 2003) (quoting *Daubert*, 509 U.S. at 593-94).

Despite these factors, "[t]he inquiry to be undertaken by the district court is 'a flexible one' focusing on the 'principles and methodology' employed by the expert, not on the conclusions reached." *Westberry*, 178 F.3d at 261 (quoting *Daubert*, 509 U.S. at 594-95); *see also Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 150 (1999) ("We agree with the Solicitor General that '[t]he factors identified in *Daubert* may or may not be pertinent in assessing reliability, depending on the nature of the issue, the expert's particular expertise, and the subject of his testimony.'" (citation omitted)); *see also Crisp*, 324 F.3d at 266 (noting "that testing of reliability should be flexible and that *Daubert*'s five factors neither necessarily nor exclusively apply to every expert").

With respect to relevancy, *Daubert* also explains:

> Expert testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful. The consideration has been aptly described by Judge Becker as one of "fit." "Fit" is not always obvious, and scientific validity for one purpose is not necessarily scientific validity for other, unrelated purposes. . . . Rule 702's "helpfulness"

> standard requires a valid scientific connection to the pertinent inquiry as a precondition to admissibility.

Daubert, 509 U.S. at 591-92 (citations and internal quotation marks omitted). At bottom, the court has broad discretion to determine whether expert testimony should be admitted or excluded. *Cooper*, 259 F.3d at 200.

III. Discussion

Dr. Patrick Culligan is an urogynecologist whose clinical practice focuses on the treatment of women with pelvic floor disorders, including incontinence and POP. Bard offers Dr. Culligan as an expert witness on the general safety and effectiveness of the Align and Avaulta products it manufactures. The plaintiffs move to exclude some of Dr. Culligan's opinions on the grounds that his applied methodology is unreliable. I address the plaintiffs' objections in turn.

A. Opinions on the Safety and Efficacy of the Align and Avaulta Products

According to the plaintiffs, Dr. Culligan's opinions on the safety and efficacy of the mesh products rely, in part, on data collected from an alternative sling device produced by a different manufacturer. In the plaintiffs' view, this data cannot form a reliable basis for Dr. Culligan's opinion given his inability "to provide support for his assumption that the Align device was clinically or materially similar" to the other devices. *See* Memo. in Supp. of Pls. General Mot. to Exclude Certain Ops. & Test. of Patrick Culligan, M.D. ("Pls.' Memo. in Supp."), at 4 [ECF No. 4564].

I find this argument unavailing because Dr. Culligan establishes the requisite connection between the alternative devices and his opinions on the Align and the Avaulta . *See* Pls.' General Mot. to Exclude Certain Ops. & Test. of Patrick Culligan,

M.D., Ex. A ("Dr. Culligan's Expert Report"), at 11, 13 [ECF No. 4563-1]; *id.*, Ex. C ("Culligan Dep.") 55:16 – 56:1 [ECF No. 4563-2]. Moreover, Dr. Culligan's method is not unreliable just because a direct comparison study does not exist between these products. *See Winebarger v. Bos. Sci. Corp.*, No. 2:13-cv-28892, 2015 WL 1887222, at *32 (S.D. W. Va. April 24, 2015); *see also Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 720 (S.D. W. Va. 2014) ("Ethicon incorrectly asserts that these studies are irrelevant because [Ethicon] did not review the TVT–O specifically."). The plaintiffs' remaining objections on this matter go to credibility, not admissibility, and are better suited for cross-examination. *See Daubert*, 509 U.S. at 596 ("Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence.").

Therefore, the plaintiffs' motion on this point is **DENIED**.

B. Opinions that Bard's Decision to Design and Market the Align and Avaulta Products Was Reasonable and Appropriate

Dr. Culligan also opines that "Bard's decision to design and market the Align slings was reasonable and appropriate." Dr. Culligan's Expert Report, at 11. The plaintiffs contend that any testimony pertaining to the reasonableness of Bard's decision-making lacks foundation and impermissibly encroaches upon the province of the fact-finder; I agree.

As I have stated previously, Bard's knowledge, state of mind, or other matters related to corporate conduct are not appropriate subjects of expert testimony because opinions on these matters will not assist the jury. *See, e.g.*, *In re Fosamax Prods. Liab. Litig.*, 645 F. Supp. 2d 164, 192 (S.D.N.Y. 2009) (precluding testimony as to "the

knowledge, motivations, intent, state of mind, or purposes of" a company and its employees because it "is not a proper subject for expert or even lay testimony"). Likewise, opinions that state a legal standard usurp the jury's role and will not be accepted at trial. *See United States v. McIver*, 470 F.3d 550, 562 (4th Cir. 2006) ("[O]pinion testimony that states a legal standard or draws a legal conclusion by applying law to the facts is generally inadmissible."); *see also Perez v. Townsend Eng'g Co.*, 562 F. Supp. 2d 647, 652 (M.D. Pa. 2008) (precluding an expert witness "from using legal terms of art" and "giv[ing] legal conclusions, such as, but not limited to, the conclusions that the [product] was 'defective,' 'unreasonably dangerous,' or was the 'proximate cause' of [the plaintiff's] injury").

This part of the plaintiffs' motion is therefore **GRANTED** and this opinion is **EXCLUDED**.

C. Opinions Regarding the Information for Use ("IFU") Warnings

The plaintiffs next challenge Dr. Culligan's opinion that the IFUs corresponding with the Avaulta Solo and the Align devices adequately warn physicians of the risks associated with these devices. This opinion, in the plaintiffs' view, is beyond Dr. Culligan's expertise because he acknowledges that he had no direct involvement in drafting the IFU for either the Align or Avaulta products. *See* Pls.' Memo. in Supp., at 7 (citing Culligan Dep. 43:2-8). The plaintiffs also object to Dr. Culligan's opinions regarding the feasibility and utility of the information contained in the IFU; specifically, his assertion that it would be "impossible" for Bard

to provide an updated list of complication rates and, even if it were feasible, it would nonetheless "not be useful." *Id.* (citing Culligan Dep. 49:7-14).

In response, Bard argues that the plaintiffs' objections fail to contest Dr. Culligan's qualifications to opine on the subject generally; qualifications it beleives are sufficient.

As the parties note in their respective briefs, Dr. Culligan has undergone this court's *Daubert* gantlet before on numerous occasions. As it relates to the instant dispute, the court previously held that Dr. Culligan is not qualified to opine on matters related to IFUs. *See Tyree v. Bos. Sci. Corp.*, No. 2:12-cv-08633, 2014 WL 5486694, at *68 (S.D. W. Va. Oct. 29, 2014). Of particular importance, the court found decisive Dr. Culligan's acknowledgment that his "experience" in drafting IFUs consisted merely of hiring a consultant to draft an IFU and that his only responsibility was to "just work[] on the specific wording for that document." *Id.*

Here, Bard has not presented any new evidence or otherwise persuaded this court to deviate from its prior conclusion. Therefore, I **ADOPT** my prior holding and **FIND** that Dr. Culligan does not have the "knowledge, skill, experience, training, or education" to opine as to the adequacy, feasibility, or utility of the information contained within an IFU. Fed. R. Evid. 702. Therefore, the plaintiffs' motion on this point is **GRANTED** and these opinions are **EXCLUDED.**

D. Opinions on Surgical Wound Contraction

The plaintiffs raise similar objections to Dr. Culligan's opinion that "[s]urgical wounds and surgical procedures, in general, undergo a healing process . . . that result

in a certain amount of scarification and therefore a certain amount of tissue contracture *with or without mesh material*' is normal. Pls.' Memo. in Supp., at 9 (citing Culligan Dep., at 64:22 – 65:2 (emphasis added)). Recognizing this court's prior holdings on this subject in favor of the defendants, the plaintiffs do not seek this opinion in its entirety. Rather, the plaintiffs seek to exclude Dr. Culligan from testifying on the narrow issue of whether contracture occurs "regardless of the presence of mesh." *See* Pls. Memo. in Supp., at 9. Bard does not appear to respond directly to the plaintiffs' challenge.

Limited in this way, and in the absence of context in which this narrow opinion will be presented at trial, the court does not have enough information to judge the reliability of this particular opinion. Accordingly, I **RESERVE** ruling until further testimony may be offered and evaluated firsthand at trial.

E. Opinions Regarding the Physical Properties of Polypropylene Mesh

The plaintiffs next argue that Dr. Culligan is not qualified to offer any opinions related to the physical properties of polypropylene, including issues related to degradation, contraction, and pore size. In short, the plaintiffs rely on this court's previous finding in *Tyree v. Bos. Sci. Corp.*, 54 F. Supp. 3d 501, 581 (S.D. W. Va. 2014), which held that Dr. Culligan's opinion on this issue lacked a reliable scientific methodology because his clinical observations of excised mesh, which supported his opinion, were too general.

In response, Bard relies on this court's holding in *Sanchez v. Bos. Sci. Corp.*, No. 2:13-CV-04891, 2016 WL 2962223, at *11 (S.D. W. Va. May 20, 2016). In *Sanchez*,

entered over year after *Tyree*, this court reserved for trial a determination on the reliability of Dr. Culligan's opinions until further testimony may be offered because it neither had enough information to judge the reliability or relevance of these his clinical observations, nor a basis to assess whether his claims are supported by the scientific community.

Here, the plaintiffs' citations to Dr. Culligan's deposition testimony alone does not persuade this court to adopt the reasoning articulated in *Tyree* over the rationale in *Sanchez*.

Accordingly, I **RESERVE** ruling until further testimony may be offered and evaluated first-hand at trial.

F. Opinions Concerning the Material Safety Data Sheet ("MSDS")

The plaintiffs seek to prevent Dr. Culligan from testifying regarding the utility and interpretation of language contained in the MSDS corresponding to the polypropylene used by Bard to manufacture its medical devices.

The pertinent issue is not whether doctors rely on or heed MSDS warnings for the raw materials Bard uses. *See Tyree v. Bos. Sci. Corp.*, 54 F. Supp. 3d 507, 577 (S.D. W. Va. 2014) (excluding a doctor's opinions on the MSDS because "[a] narrative review of the history and development of MSDSs and who uses them in the field is not helpful to the jury"). Nevertheless, I acknowledge the need for rebuttal testimony based on what the plaintiffs present at trial. Accordingly, I **RESERVE** ruling on the admissibility of Dr. Culligan's MSDS opinions for trial.

G. Opinions Concerning the Safety, Efficacy, or Acceptance of the Mesh Products

Next, the plaintiffs object to Dr. Culligan's opinions regarding the general safety and efficacy of the mesh products to the extent these opinions rely upon position statements published by the American Urogynecologic Society and the American Urological Association (the "Position Statement"). *See* Pls. Memo. in Supp., at 12-13.

As an initial matter, I agree that Bard cannot use Dr. Culligan as a mouthpiece for the Position Statement—simply reading a document into evidence does not require "scientific, technical, or other specialized knowledge." Fed. R. Evid. 702. Nor can Dr. Culligan represent to the jury that the Position Statement embodies a legal conclusion or a standard of care. *See United States v. McIver*, 470 F.3d 550, 572 (4th Cir. 2006) ("[O]pinion testimony that states a legal standard . . . is generally inadmissible."). To the extent Dr. Culligan seeks to use the Position Statement in this manner, his opinions are **EXCLUDED**.

The plaintiffs also argue that a Position Statement "is not a reliable scientific basis for any expert opinion" because it is not helpful to the trier of fact. *See* Memo. in Supp. of Pls. General Mot. to Exclude Certain Ops. & Test. of Patrick Culligan, M.D., at 13. Even if this is true, the unreliability of one source used by an expert in reaching his opinion does not call for the exclusion of that opinion altogether, assuming the expert considered other reliable sources in his methodology. Therefore, to the extent the plaintiffs seek to exclude any of Dr. Culligan's opinions merely because he relied, in part, on the Position Statement, their motion is **DENIED**.[1]

[1] The plaintiffs also seem to argue that Dr. Culligan should not be permitted to reference the Position Statement at all. This argument goes to the admissibility of the Position Statement, rather than the

H. Opinions Regarding FDA Regulatory Compliance

I have repeatedly excluded evidence regarding the FDA's section 510(k) clearance process in these MDLs. For the same reasons articulated in dozens of opinions available to the parties, expert testimony related to the section 510(k) process, including subsequent enforcement actions and discussion of the information Bard did or did not submit in its section 510(k) application, is **EXCLUDED.** Opinions about Bard's compliance with or violation of the FDA's labeling and adverse event reporting regulations are **EXCLUDED**. Therefore, as it relates to this issue, the plaintiffs' motion is **GRANTED.**

IV. Conclusion

For the reasons stated above, the court **ORDERS** that the plaintiffs' *Daubert* Motion to Exclude Certain Opinions and Testimony of Patrick Culligan [ECF No. 4563] is **GRANTED in part**, **DENIED in part**, and **RESERVED in part**.

The court **DIRECTS** the Clerk to file a copy of this Memorandum Opinion and Order in 2:10-md-2187, and the Bard Wave 4 and Wave 5 cases identified in the Exhibit attached hereto. The court further **DIRECTS** the Clerk to send a copy of this Order to counsel of record and any unrepresented party.

ENTER: September 4, 2018

JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE

admissibility of Dr. Culligan opinions, and is therefore better suited for a motion *in limine*. Accordingly, I do not address it at this time.

Exhibit A

CIVIL ACTION NUMBER	Case Name
2:14-cv-03439	Kitchen v. C. R. Bard, Inc. et al.
2:14-cv-18890	McManus v. C. R. Bard, Inc. et al.
2:14-cv-21874	McCray v. C. R. Bard, Inc. et al.
2:14-cv-23401	Barber v. C. R. Bard, Inc. et al.
2:14-cv-28943	Smith et al. v. C. R. Bard, Inc. et al.
2:16-cv-01855	Eiffler v. Sofradim Production SAS et al.